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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte HELENE DERAND, ANDERS LARSSON, and
JAMES VAN ALSTINE

Appeal 2010-001380
Application 10/069,827
Technology Center 1700

Before BRADLEY R. GARRIS, ADRIENE LEPIANE HANLON, and TERRY J. OWENS, *Administrative Patent Judges*.

OWENS, *Administrative Patent Judge*.

DECISION ON APPEAL[1]

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the "MAIL DATE" (paper delivery mode) or the "NOTIFICATION DATE" (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

STATEMENT OF THE CASE

The Appellants appeal under 35 U.S.C. § 134(a) from the Examiner's rejection of claims 2-5, 7, 8, 10-28, 30, 34, 35, 42, 43, 45 and 54, which are all of the pending claims. We have jurisdiction under 35 U.S.C. § 6(b).

The Invention

The Appellants claim a microfluidic device and a method for using it to perform an analytical assay. Claims 7 and 30 are illustrative:

> 7. A microfluidic device being in a dry state that is capable of being rehydrated, said device comprises a set of one or more covered microchannel structures manufactured in the surface of a planar substrate, wherein each microchannel structures comprises:
>
> a) more than one functional part wherein at least one of said functional parts is selected from the group consisting of a volume defining unit, a mixing cavity, and a waste cavity;
>
> b) wherein reduced non-specific adsorption and hydrophilicity have been optimized by a coating exposing a non-ionic hydrophilic polymer on the surface of at least one of said at least one functional parts such that an aqueous liquid is capable of entering the functional part by self-suction when the liquid has passed the entrance of the functional part; and
>
> c) wherein the device is adapted for mass transport of solutes and/or particles between different functional parts of each microchannel structure by a liquid flow caused by non-electrokinetic forces.
>
> 30. A method of performing an analytical assay in a microchannel structure of the microfluidic device of claim 7 comprising the steps of:
>
> (a) preparing a sample;

(b) transporting an analyte and reagents between different function parts of the microchannel structure by a liquid flow caused by non-electrokinetic forces and running the assay reaction within the device; and

(c) detecting within the device the result of the assay reaction, wherein the result is a measure of an activity and/or a quantitative presence of an analyte in the sample.

The References

Van Alstine	4,690,749	Sept. 1, 1987
Bergstrom	5,250,613	Oct. 5, 1993
Karger	5,840,388	Nov. 24, 1998
Amigo	5,935,401	Aug. 10, 1999
Regnier	5,958,202	Sept. 28, 1999
Daecher	6,183,829 B1	Feb. 6, 2001
Zimmer[2]	DE 197 53 847	Dec. 4, 1997

Martin Malmsten et al. (Malmsten), "Effect of Chain Density on Inhibition of Protein Adsorption by Poly(ethylene glycol) Based Coatings", 202 *J. Colloid & Interface Sci.* 501-17 (1998).

The Rejections

The claims stand rejected under 35 U.S.C. § 103 as follows: claims 2-5, 7, 8, 10-13, 18-23, 28, 30, 34, 35, 42, 43 and 54 over Amigo in view of Zimmer, Karger and Regnier, claims 14 and 24-26 over Amigo in view of Zimmer, Karger, Regnier and Bergstrom, claims 15-17 over Amigo in view of Zimmer, Karger, Regnier and Malmsten, claim 45 over Amigo in view of Zimmer, Karger, Regnier and Daecher, and claims 7 and 27 over Karger in view of Zimmer, Van Alstine and Regnier.

[2] The Examiner (Ans. 3) and the Appellants (Br. 7) rely upon an English language equivalent of Zimmer, i.e., US 7,008,799 B1 to Zimmer et al. (issued Mar. 7, 2006, ¶ 371 (c)(1), (2), (4) date Sept. 19, 2000).

OPINION

We reverse the rejections. We need to address only the independent claims (7 and 30).[3]

Issue

Have the Appellants indicated reversible error in the Examiner's determination that the applied prior art would have rendered prima facie obvious, to one of ordinary skill in the art, 1) a device adapted for mass transport of solutes and/or particles between different functional parts of a microchannel structure by a liquid flow caused by non-electrokinetic forces (claim 7), or 2) a step of transporting an analyte and reagents between different functional parts of a microchannel structure by a liquid flow caused by non-electrokinetic forces (claim 30)?

Findings of Fact and Analysis

Rejection over Amigo in view of Zimmer, Karger and Regnier

"[D]uring examination proceedings, claims are given their broadest reasonable interpretation consistent with the specification." *In re Translogic Tech. Inc.*, 504 F.3d 1249, 1256 (Fed. Cir. 2007), *quoting In re Hyatt*, 211 F.3d 1367, 1372 (Fed. Cir. 2000).

The Examiner argues that "Applicant's disclosure gives absolutely no indication that a non-electrokinetic means of fluid movement is a significant part of the claimed invention" (Ans. 9).

That is incorrect. The Appellants' Specification states that "[s]ole capillaries, possibly with an area for application and an area for detection, as

[3] The Examiner does not rely upon Bergstrom, Malmsten or Daecher for any disclosure that remedies the deficiency in Amigo, Zimmer, Karger and Regnier as to the independent claims (Ans. 10-14).

used in capillary electrophoresis in which solutes are caused to migrate by an applied electric field for separation purposes are not microfluidic devices as contemplated in the context of the invention" (Spec. 2:1-6).

The Examiner argues that "[t]he disclosure at Page 13, lines 4-22 describes suitable means of causing fluid flow, and lists electrokinetic means (e.g. electroendoosmosis and electrophoresis) and non-electrokinetic means, with no indication that either is preferable" (Ans. 9).

The Appellants' Specification states that "[a]n electrophoresis capillary may, however, be part of a microfluidic device if the capillary is part of a microchannel structure in which there are one or more additional functional parts from and/or to which mass transport of a solute by a liquid flow is taking place as defined above" (Spec. 2:6-11). Thus, the Appellants' microfluidic device adapted for mass transport of solutes and/or particles between different functional parts of each microchannel structure by liquid flow caused by non-electrokinetic forces can include an electrophoresis capillary provided that the electrophoresis capillary is a functional part of the device that is in addition to the microchannel structure in which liquid flow is caused by non-electrokinetic forces. The portion of the Appellants' Specification relied upon by the Examiner includes the following (Spec. 13:8-22):

> The liquid flow may be driven by capillary forces, and/or centripetal force, pressure differences applied externally over a microchannel structure and also other non-electrokinetic forces that are externally applied and cause transport of the liquid and the analytes and reagents in the same direction. The liquid flow may also be driven by pressure generated by electroendoosmosis created within the structure. . . . The liquid flow may be paused when a reagent and/or analyte have reached a preselected part in which they are subjected to a

> certain procedure, for instance capillary electrophoresis in a separation part, a reaction in a reaction part, detection in a detection part etc.

Thus, the Appellants' Specification indicates that in part of the microchannel structure the liquid flow must be driven by non-electrokinetic forces but also may be driven by pressure generated by electroendoosmosis created within the structure, whereas flow driven by capillary electrophoresis is limited to a different part of the structure, e.g., a separation part.

Accordingly, the broadest reasonable interpretation of "mass transport of solutes and/or particles between different functional parts of each microchannel structure by a liquid flow caused by non-electrokinetic forces" (claim 7) in view of the Appellants' Specification is that the capability of such liquid flow caused by non-electrokinetic forces must exist in some part of the microchannel structure, and the broadest reasonable interpretation of "transporting an analyte and reagents between different function[al] parts of the microchannel structure by a liquid flow caused by non-electrokinetic forces" (claim 30) is that liquid flow must take place between different functional parts of the microchannel structure caused by non-electrokinetic forces.

The Examiner argues that Amigo "discloses such non-electrokinetic fluid transport in preparing the device. (Column 9, lines 45-48)" (Ans. 9).

Amigo discloses electrophoretic chambers which "find use [in] a variety of electrophoretic applications in which entities are moved through a medium under the influence of an applied electric field" (abstract). The portion of Amigo relied upon by the Examiner discloses that excess amounts of the first of two monomers applied to form a hydrophilic coating on the chamber surface "may be removed using any convenient means, such as

wiping, washing, flushing nitrogen or air under pressure and the like" (col. 9, ll. 45-48). That portion does not indicate that the device is capable of transporting analyte and reagents between different functional parts of each microchannel structure by a liquid flow caused by non-electrokinetic forces.

The Examiner argues that "Regnier et al[.] disclose bulk fluid motion caused by non-electrokinetic means (Column 37, lines 53-59)" (Ans. 8). The Appellants argue that one of ordinary skill in the art would not have considered such bulk flow to be needed in Amigo's electrophoresis process wherein movement is through a medium as a result of an applied electric field (Br. 19).

Regnier discloses an electrophoretic device (abstract). The portion of Regnier relied upon by the Examiner states that "[t]he sample or reactant volumes may be introduced by any of the methods employed in capillary electrophoretic systems, including hydrodynamic, electrokinetic, vacuum, injection port, and syringe methods" (col. 37, ll. 54-57). The Examiner has not established that such methods for introducing a sample into an electrophoretic device indicates that the device is capable of transporting analyte and reagents between different functional parts of each microchannel structure by liquid flow caused by non-electrokinetic forces rather than the disclosed electrophoresis.

Rejection over Karger in view of Zimmer, Van Alstine and Regnier

Karger discloses an electrophoretic device (abstract). The Examiner argues that "[i]t would also have been obvious to one having ordinary skill in the art to further modify the device of Karger et al[.] by using a non-electrokinetic means of moving fluid within the channels, as also taught by

Regnier et al[.], because it would prevent electrophoretic bias in the injection procedure" (Ans. 16). The portion of Regnier relied upon by the Examiner for a disclosure of bulk flow motion caused by non-electrokinetic forces is the same as that discussed above (col. 37, ll. 53-59) (Ans. 15).

The Appellants argue that "the rejection is grounded on an unsubstantiated and unexplained motivation to combine" (Br. 30).

The Examiner's argument is limited to the injection of fluid into Karger's device. The Examiner has not established that the relied-upon references would have led one of ordinary skill in the art to modify Karger's electrophoretic device such that it is capable of transporting analyte and reagents between different functional parts of each microchannel structure by liquid flow caused by non-electrokinetic forces rather than the disclosed electrophoresis.

Conclusion

The Appellants have indicated reversible error in the Examiner's determination that the applied prior art would have rendered prima facie obvious, to one of ordinary skill in the art, 1) a device adapted for mass transport of solutes and/or particles between different functional parts of a microchannel structure by a liquid flow caused by non-electrokinetic forces (claim 7), and 2) a step of transporting an analyte and reagents between different functional parts of a microchannel structure by a liquid flow caused by non-electrokinetic forces (claim 30).

DECISION/ORDER

The rejections under 35 U.S.C. § 103 of claims 2-5, 7, 8, 10-13, 18-23, 28, 30, 34, 35, 42, 43 and 54 over Amigo in view of Zimmer, Karger and Regnier, claims 14 and 24-26 over Amigo in view of Zimmer, Karger,

Regnier and Bergstrom, claims 15-17 over Amigo in view of Zimmer, Karger, Regnier and Malmsten, claim 45 over Amigo in view of Zimmer, Karger, Regnier and Daecher, and claims 7 and 27 over Karger in view of Zimmer, Van Alstine and Regnier are reversed.

It is ordered that the Examiner's decision is reversed.

REVERSED

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